



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

7

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/302,863	04/30/1999	RAYMOND G. GOODWIN	2519-US-NP	7568
22932	7590	05/01/2007		
IMMUNEX CORPORATION LAW DEPARTMENT 1201 AMGEN COURT WEST SEATTLE, WA 98119			EXAMINER ROMEO, DAVID S	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 05/01/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/302,863

**Applicant(s)**

GOODWIN ET AL.

**Examiner**

David S. Romeo

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-30,32,35 and 37-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-30,32,35 and 37-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The amendment filed 02/08/2007 has been entered. Claims 15–30, 32, 35 and 37–40 are pending and being examined.

#### Maintained Formal Matters, Objections, and/or Rejections:

5           The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10           (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15           Claims 15–16, 19–21, 23–25, 27–30, 32, 35, and 37–40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (U. S. Publication No. 20060067933) in view of Bram (WO 98/39361) and Yu (WO 98/18921).

20           Claims 15 and 25–26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Bram and Yu as applied to claims 15, 25, and 35 above, and further in view of Nocka (U. S. Patent No. 5,525,708).

25           Claims 15 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Bram and Yu as applied to claim 15 above, and further in view of Creighton (1984).

Art Unit: 1647

Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Bram and Yu as applied to claim 15 above, and further in view of Alberts (1983) and Hu (U. S. Patent No. 5,932,540).

5            Claims 15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Bram and Yu and further in view of Alberts (1983) and Hu (U. S. Patent No. 5,932,540) as applied to claims 15 and 17 above and further in view of Ullman (U. S. Patent No. 5,340,716).

*Response to Arguments*

10           Applicants argue that:

         Applicants have amended Claims 15, 29, 30, 32, and 40 to specify that the affinity constant for TACI (SEQ ID NO:2) and TACI-L (SEQ ID NO:4) used in the screening methods is from  $1.53 \times 10^{-9}$  to  $2.2 \times 10^{-9}$ . Support for the amendments may be found at page 15, lines 5-12. Applicants submit that no new matter has been added.

15           Gross, Bram, and Yu do not teach or suggest that the affinity constant for TACI and TACI-L is from  $1.53 \times 10^{-9}$  to  $2.2 \times 10^{-9}$ . Applicants note that Gross teaches at paragraph [0110], Table 5 that the affinity constant for a soluble form of Neutrokin  $\alpha$  (aka ztnf4, TACI-L) and TACI-expressing BHK cells is  $1.11 \times 10^{-9}$ , which is outside the range in Applicants' claimed invention.

20           Applicants' arguments have been fully considered but they are not persuasive. The TACI and TACI-L taught by the prior art are identical to the TACI and TACI-L, respectively, in the present claims. A chemical composition and its properties are inseparable. Therefore, the properties applicant discloses and/or claims, i.e., "the affinity constant for protein (i) and protein (ii) is from  $1.53 \times 10^{-9}$  to  $2.2 \times 10^{-9}$ ", are necessarily present in TACI and TACI-L taught by the prior art. The affinity taught by Bram and the affinities taught by applicants are comparable. The differences in affinity may be accounted for by variability in experimental design or

Art Unit: 1647

reagents. For example, as shown in examples 4 and 5, applicants obtained different affinities for the TACI/TACI-L interaction depending on the experimental design or reagents.

### *Conclusion*

No claims are allowable.

5           **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after  
10 the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

15           ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISORS, JANET ANDRES OR GARY NICKOL, CAN BE REACHED ON (571)272-0867 OR (571)272-0835, RESPECTIVELY.

20           IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

25           ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

30           

DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

35           DSR  
APRIL 24, 2007